

CLAIMS

What is claimed is:

- 5 comprising:
1. An immunomodulatory polynucleotide/microcarrier (IMP/MC) complex,
a polynucleotide linked to a biodegradable microcarrier (MC), wherein said
polynucleotide comprises the sequence 5'-C, G-3' and wherein said MC is less than
10 $10\ \mu\text{m}$ in size.
 2. The IMP/MC complex of claim 1, wherein said polynucleotide is
covalently linked to said microcarrier.
 3. The IMP/MC complex of claim 1, wherein said polynucleotide is non-
covalently linked to said microcarrier.
 4. The IMP/MC complex of claim 1, wherein said microcarrier is a liquid
phase microcarrier.
 - 15 5. The IMP/MC complex of claim 1, wherein said microcarrier is a solid
phase microcarrier.
 6. The IMP/MC complex of claim 1, wherein said microcarrier is from 25
nm to $5\ \mu\text{m}$ in size.
 7. The IMP/MC complex of claim 6, wherein said microcarrier is from 1.0
20 μm to $2.0\ \mu\text{m}$ in size.
 8. The IMP/MC complex of claim 7, wherein said microcarrier is $1.4\ \mu\text{m}$ in
size.
 9. The IMP/MC complex of claim 1, wherein said microcarrier is cationic.
 10. The IMP/MC complex of claim 1, wherein said complex is antigen-free.
 - 25 11. The IMP/MC complex of claim 1, wherein said polynucleotide comprises
the sequence 5'-T, C, G-3'.
 12. The IMP/MC complex of claim 11, wherein said polynucleotide
comprises the sequence 5'-TCGX₁X₂X₃X₄-3' or the sequence 5'-X₁TCGX₂X₃X₄-3',
wherein X₁, X₂, X₃, X₄ are nucleotides.

13. The IMP/MC complex of claim 12, wherein said polynucleotide comprises the sequence 5'-TCGTCGX₁-3', wherein X₁ is a nucleotide.

14. The IMP/MC complex of claim 12, wherein said polynucleotide comprises a sequence selected from the group consisting of 5'-TCGTCGA-3', 5'-TCGAAAA-3', 5'-TCGCCCC-3', 5'-TCGGGGG-3' and 5'-TCGTTTT-3'.

15. The IMP/MC complex of claim 1, wherein said polynucleotide comprises the sequence 5'-C, G, pyrimidine, pyrimidine, C, G-3'.

16. The IMP/MC complex of claim 1, wherein said polynucleotide comprises the sequence 5'-purine, purine, C, G, pyrimidine, pyrimidine, C, G-3'.

17. The IMP/MC complex of claim 11, wherein said polynucleotide comprises the sequence SEQ ID NO:1.

18. The IMP/MC complex of claim 1, wherein said polynucleotide further comprises the sequence 5'-T, C, G-3'.

19. The IMP/MC complex of any of claims 1, 11, 12, 13, 14, or 18, wherein said polynucleotide is 7 nucleotides in length.

20. The IMP/MC complex of any of claims 1, 11, 12, 13, 14 or 18, wherein said complex further comprises an antigen.

21. The IMP/MC complex of claim 20, wherein said antigen is an allergen.

22. The IMP/MC complex of claim 1, wherein said polynucleotide comprises a phosphate backbone modification.

23. The IMP/MC complex of claim 22, wherein said phosphate backbone modification is a phosphorothioate.

24. A method of modulating an immune response in an individual comprising administering to an individual a composition comprising an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, said complex comprising a polynucleotide linked to a biodegradable microcarrier (MC), wherein said polynucleotide comprises the sequence 5'-C, G-3' and wherein said MC is less than 10 μm in size, in an amount sufficient to modulate an immune response in said individual.

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25. The method of claim 24, wherein said microcarrier is a solid phase microcarrier.

26. The method of claim 24, wherein said microcarrier is a liquid phase microcarrier.

5 27. The method of claim 24, wherein said polynucleotide is covalently linked to said microcarrier.

28. The method of claim 24, wherein said polynucleotide is non-covalently linked to said microcarrier.

29. The method of claim 24, wherein said complex is antigen-free.

10 30. The method of claim 24, wherein a Th1-type immune response is stimulated.

31. The method of claim 24, wherein a Th2-type immune response is suppressed.

15 32. The method of claim 24, wherein interferon-gamma (IFN- γ) is increased in said individual.

33. The method of claim 24, wherein interferon-alpha (IFN- α) is increased in said individual.

34. The method of claim 24, wherein levels of IgE is reduced in said individual.

20 35. The method of claim 24, wherein said polynucleotide comprises the sequence 5'-T, C, G-3'.

36. The method of claim 35, wherein said polynucleotide comprises the sequence 5'-TCGX₁X₂X₃X₄-3' or the sequence 5'-X₁TCGX₂X₃X₄-3', wherein X₁, X₂, X₃, X₄ are nucleotides.

25 37. The method of claim 36, wherein the polynucleotide comprises the sequence 5'-TCGTCGX₁-3', wherein X₁ is a nucleotide.

38. The method of claim 36, wherein said polynucleotide comprises a sequence selected from the group consisting of 5'-TCGTCGA-3', 5'-TCGAAAA-3', 5'-TCGCCCC-3', 5'-TCGGGGG-3' and 5'-TCGTTTT-3'.

FOOTNOTES CONTAINED HEREIN

39. The method of claim 24, wherein said polynucleotide comprises the sequence 5'-C, G, pyrimidine, pyrimidine, C, G-3'.

40. The method of claim 24, wherein said polynucleotide comprises the sequence 5'-purine, purine, C, G, pyrimidine, pyrimidine, C, G-3'.

5 41. The method of claim 35, wherein said polynucleotide comprises the sequence SEQ ID NO:1.

42. The method of claim 24, wherein said polynucleotide further comprises the sequence 5'-T, C, G-3'.

10 43. The method of any of claims 24, 35, 36, 37, 38 or 42, wherein said polynucleotide is 7 nucleotides in length.

44. The method of any of claims 24, 35, 36, 37, 38 or 42, wherein said composition further comprises an antigen.

45. The method of claim 44, wherein said antigen is an allergen.

15 46. The method of claim 24, wherein said polynucleotide comprises a phosphate backbone modification.

47. The method of claim 46, wherein said phosphate backbone modification is a phosphorothioate.

48. A kit, comprising:

20 an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, said complex comprising a polynucleotide linked to a biodegradable microcarrier (MC), wherein said polynucleotide comprises the sequence 5'-C, G-3' and wherein said MC is less than 10 μ m in size.

49. The kit of claim 48, wherein said polynucleotide is covalently linked to said microcarrier.

25 50. The kit of claim 48, wherein said polynucleotide is non-covalently linked to said microcarrier.

51. The kit of claim 48, wherein said microcarrier is a liquid phase microcarrier.

30 52. The kit of claim 48, wherein said microcarrier is a solid phase microcarrier.



53. The kit of claim 48, wherein said microcarrier is from 25 nm to 5 μ m in size.

54. The kit of claim 53, wherein said microcarrier is from 1.0 μ m to 2.0 μ m in size.

5 55. The kit of claim 54, wherein said microcarrier is 1.4 μ m in size.

56. The kit of claim 48, wherein said microcarrier is cationic.

57. The kit of claim 48, wherein said complex is antigen-free.

58. The kit of claim 48, wherein said polynucleotide comprises the sequence 5'-T, C, G-3'.

10 59. The kit of claim 58, wherein said polynucleotide comprises the sequence 5'-TCGX₁X₂X₃X₄-3' or the sequence 5'-X₁TCGX₂X₃X₄-3', wherein X₁, X₂, X₃, X₄ are nucleotides.

60. The kit of claim 59, wherein said polynucleotide comprises the sequence 5'-TCGTCGX₁-3', wherein X₁ is a nucleotide.

15 61. The kit of claim 59, wherein said polynucleotide comprises a sequence selected from the group consisting of 5'-TCGTCGA-3', 5'-TCGAAAA-3', 5'-TCGCCCC-3', 5'-TCGGGGG-3' and 5'-TCGTTTT-3'.

62. The kit of claim 48, wherein the polynucleotide comprises the sequence 5'-C, G, pyrimidine, pyrimidine, C, G-3'.

20 63. The kit of claim 48, wherein the polynucleotide comprises the sequence 5'-purine, purine, C, G, pyrimidine, pyrimidine, C, G-3'.

64. The kit of claim 58, wherein the polynucleotide comprises the sequence SEQ ID NO:1.

25 65. The kit of claim 48, wherein said polynucleotide further comprises the sequence 5'-T, C, G-3'.

66. The kit of any of claims 48, 58, 59, 60, 61 or 65, wherein said kit further comprises an antigen.

67. The kit of claim 66, wherein said antigen is an allergen.

30 68. The kit of claim 48, wherein said polynucleotide comprises a phosphate backbone modification.

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69. The kit of claim 68, wherein said phosphate backbone modification is a phosphorothioate.

70. A kit, comprising:

5 an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, said complex comprising a polynucleotide linked to a biodegradable microcarrier (MC), wherein said polynucleotide comprises the sequence 5'-C, G-3' and wherein said polynucleotide is 7 nucleotides in length.

71. The kit of claim 70, wherein said polynucleotide comprises the sequence 5'-T, C, G-3'.

10 72. The kit of claim 71, wherein said polynucleotide consists of the sequence 5'-TCGX₁X₂X₃X₄-3' or the sequence 5'-X₁TCGX₂X₃X₄-3', wherein X₁, X₂, X₃, X₄ are nucleotides.

73. The kit of claim 72, wherein said polynucleotide consists of the sequence 5'-TCGTCGX₁-3', wherein X₁ is a nucleotide.

15 74. The kit of claim 72, wherein said polynucleotide consists of a sequence selected from the group consisting of 5'-TCGTCGA-3', 5'-TCGAAAA-3', 5'-TCGCCCC-3', 5'-TCGGGGG-3' and 5'-TCGTTTT-3'.

75. The kit of claim 70, wherein said polynucleotide further comprises the sequence 5'-T, C, G-3'.

20 76. The kit of claim 70, wherein said complex is antigen-free.

77. The kit of claim 70, further comprising an antigen.

78. The kit of claim 77, wherein said antigen is an allergen.

79. The kit of claim 70, wherein said polynucleotide comprises a phosphate backbone modification.

25 80. The kit of claim 79, wherein said phosphate backbone modification is a phosphorothioate.

81. A composition comprising an IMP/MC complex of claim 1 and a pharmaceutically acceptable excipient.

30 82. A composition according to claim 81, wherein the composition is antigen-free.

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83. A composition according to claim 81, wherein the composition further comprises an antigen.

84. A composition according to claim 83, wherein the antigen is an allergen.

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